



Patent
Dkt. 13854.4004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:)	Group Art Unit: 1636
)	
Paul G. Yock, et al.)	Examiner: Marvich, Maria
)	
Serial No.: 10/776,037)	Reissue Application of U.S. Patent
)	No. 6,346,098 B1
Filed: February 9, 2004)	
)	
For: METHODS AND KITS FOR LOCALLY)	
ADMINISTERING AN ACTIVE AGENT)	
TO AN INTERSTITIAL SPACE OF A)	
HOST)	
)	

**FIRST AMENDED JOINT DECLARATION OF PAUL G. YOCK, ALI H. HASSAN,
ALAN CHING YEUN YEUNG, ANDREW CARTER, MEHRDAD REZAAE,
NIALL HERITY, SIDNEY LO, AND PETER J. FITZGERALD UNDER 37 C.F.R. 1.175**

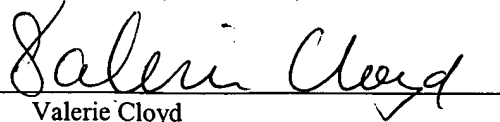
We, Paul G. Yock, Ali H. Hassan, Alan Ching Yeun Yeung, Andrew Carter, Mehrdad Rezaee, Niall Herity, Sidney Lo, and Peter J. Fitzgerald jointly declare:

1. Each of our residence address, mailing address, and countries of citizenship are stated below next to our names.

CERTIFICATE OF MAILING
(37 C.F.R. §1.8)

I hereby certify, pursuant to 37 CFR §1.8, that I have reasonable basis to expect that that this paper or fee (along with any referred to as being attached or enclosed) would be mailed or transmitted on or before the date indicated with the United States Postal Service with sufficient postage as first class mail on the date shown below in an envelope addressed to Mail Stop Reissue, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

March 16, 2006
Date of Deposit


Valerie Cloyd

2. We believe that we are the original, first, and joint inventors of the subject matter described and claimed in United States Patent No. 6,346,098 B1 (hereinafter “the ‘098 Patent”), granted on February 12, 2002, and for which a reissue patent is sought on the invention entitled “Methods and Kits for Locally Administering an Active Agent to an Interstitial Space of a Host,” the specification of which is submitted concurrently with this Declaration.

3. We do not know and do not believe that the invention was ever known in the United States of America before our invention thereof.

4. We believe the ‘098 Patent to be partly inoperative or invalid by reason of the patentee claiming more or less than patentee had the right to claim in the patent.

5. This application is, in part, a broadening reissue application, and that an explanation of the nature of the broadening is set forth below.

6. At least one error in the original claims of the ‘098 Patent upon which reissue is based is described below.

7. The original claims of the ‘098 Patent each recited a method of locally administering an active agent to a host, but that several embodiments of the methods described in the ‘098 Patent, for which we are rightfully entitled to coverage by the claims of the ‘098 Patent, were not recited in the original claims, including the following (which are recited in new dependent claims 20-36):

a. The method recited in original claim 1 wherein said agent comprises cells.

b. The method recited in original claim 1 wherein said agent is a biological agent selected from the group consisting of peptides, proteins, nucleic acids, lipids, polysaccharides, and mimetics thereof.

c. The method recited in original claim 1, wherein said agent comprises therapeutic nucleic acids.

d. The method recited in original claim 1, wherein the agent comprises therapeutic nucleic acids, and wherein the therapeutic nucleic acids comprise at least one gene.

e. The method recited in original claim 1, wherein said agent comprises a dye or an imaging agent.

f. The method recited in original claim 1, wherein said retroinfusion is performed at a pressure of at least 50 mm Hg.

g. The method recited in original claim 1, wherein said retroinfusion is performed at a pressure of at least 60 mm Hg.

h. The method recited in original claim 1, wherein said retroinfusion is performed at a pressure of at least 1000 mm Hg.

i. The method recited in original claim 5, wherein the energy administered is selected from the group consisting of ultrasound, heat, electroporation and radio frequency energy.

- j. The method recited in original claim 3, wherein said stress is chemical stress.
- k. The method recited in original claim 1, wherein said vessel is an artery.
- l. The method recited in original claim 2, wherein said retroinfusion comprises disruption of venous branches upstream of the site of administration for said agent to enter an interstitial space of said host through the disruptions in the venous branches.
- m. The method recited in original claim 1, wherein said agent is retroinfused through a catheter having an occlusion device downstream of the site of administration of said agent.
- n. The method recited in original claim 1 wherein said agent is retroinfused through a catheter having an occlusion device downstream of the site of administration of said agent, and wherein at least one upstream branch of said vessel is occluded.
- o. The method recited in original claim 2, wherein said agent is retroinfused through a catheter having an occlusion device downstream of the site of administration of said agent.
- p. The method recited in original claim 2, wherein said agent is retroinfused through a catheter having an occlusion device downstream of the site

of administration of said agent, and wherein said retroinfusion comprises disruption of venous branches upstream of the site of administration for said agent to enter an interstitial space of said host through the disruption in the venous branches.

q. The method recited in original claim 1, wherein said pressure is sufficient to at least distend said vessel.

8. The insufficiencies of the original claims of the '098 Patent set forth in paragraphs 7 and 7.a. through 7.q. are corrected by the inclusion of new claims 20 through 36, each of which recites a method of locally administering an active agent to a host comprising, *inter alia*, one of embodiments listed in paragraphs 7.a. through 7.q. that was not recited in the original claims of the '098 Patent.

9. The original claims of the '098 Patent, including independent claims 1, 8, and 13, each recite a method of locally administering an active agent to a host comprising, *inter alia*, retroinfusing said agent into a vascular vessel (claim 1) or vein (claims 8 and 13), whereas the method of locally administering an active agent of the invention described in the '098 Patent may be practiced by retroinfusing a fluid into a vascular vessel or vein followed by retroinfusing the agent, and, accordingly, that the claims thereof are insufficient because they are unnecessarily limiting.

10. The insufficiency of the original claims of the '098 Patent set forth in the paragraph 9 is corrected by the inclusion of new claims 37 through 55, each of which recites a

method of locally administering an active agent to a host comprising, *inter alia*, retroinfusing a fluid into a vascular vessel or vein to facilitate transport of an agent followed by retroinfusing the agent, thereby presenting claims that are broader in this respect than the original claims of the '098 Patent.

11. Original claim 7 of the '098 Patent recites a method of locally administering an active agent to a host comprising, *inter alia*, administering an agent at a pressure sufficient to produce at least a mechanical stress on said vessel, whereas the method of locally administering an active agent of the invention described in the '098 Patent may be practiced by retroinfusing an agent into a vascular vessel of the host under conditions sufficient to produce at least a mechanical stress on the vessel, which stress facilitates the transport of the agent through the wall of the vessel so that the agent is locally administered to the host, and, accordingly, that the claims thereof are insufficient because they do not recite the foregoing methodology.

12. The insufficiency of the original claims of the '098 Patent set forth in the paragraph 11 is corrected by the inclusion of new claims 56 through 66, each of which recites a method of locally administering an active agent to a host comprising, *inter alia*, retroinfusing an agent into a vascular vessel of the host under conditions sufficient to produce at least a mechanical stress on the vessel, which stress facilitates the transport of the agent through the wall of the vessel so that the agent is locally administered to the host.

13. The insufficiencies of the original claims of the '098 Patent set forth in paragraphs 9 and 11 are further corrected by the inclusion of new claims 78 through 89, each of which

recites a method of locally administering an active agent to a host comprising, *inter alia*, retroinfusing a fluid into a vascular vessel or vein to facilitate transport of an agent followed by retroinfusing the agent – thereby presenting claims that are broader in this respect than the original claims of the ‘098 Patent – and each of which further recites a method of locally administering an active agent to a host comprising, *inter alia*, retroinfusing an agent into a vascular vessel of the host under conditions sufficient to produce at least a mechanical stress on the vessel, which stress facilitates the transport of the agent through the wall of the vessel so that the agent is locally administered to the host.

14. Original claim 13 of the ‘098 Patent recites a method of locally administering an active agent to a host comprising, *inter alia*, administering an agent at a pressure sufficient to at least distend a vein of the host, whereas the method of locally administering an active agent of the invention described in the ‘098 Patent may be practiced by retroinfusing an agent into a vein of the host under conditions sufficient to at least distend the vein, which distension facilitates the transport of the agent through the wall of the vein so that the agent is locally administered to the host, and, accordingly, that the claims thereof are insufficient because they do not recite the foregoing methodology.

15. The insufficiency of the original claims of the ‘098 Patent set forth in paragraph 14 is corrected by the inclusion of new claims 67 through 77, each of which recites a method of locally administering an active agent to a host comprising, *inter alia*, retroinfusing an agent into a vein of the host under conditions sufficient to at least distend the vein, which distension

facilitates the transport of the agent through the wall of the vessel so that the agent is locally administered to the host.

16. The insufficiencies of the original claims of the '098 Patent set forth in paragraphs 9 and 14 are further corrected by the inclusion of new claims 90 through 100, each of which recites a method of locally administering an active agent to a host comprising, *inter alia*, retroinfusing a fluid into a vascular vessel or vein to facilitate transport of an agent followed by retroinfusing the agent – thereby presenting claims that are broader in this respect than the original claims of the '098 Patent – and each of which further recites a method of locally administering an active agent to a host comprising, *inter alia*, retroinfusing an agent into a vein of the host under conditions sufficient to at least distend the vein, which distension facilitates the transport of the agent through the wall of the vessel so that the agent is locally administered to the host.

17. The insufficiencies in the original claims of the '098 Patent identified in paragraphs 7, 7.a.-7.q., 9, 11, and 14 arose, occurred or resulted from the fact that we and our attorneys failed to communicate adequately concerning the preparation of claims and prosecution of the application that issued as the '098 patent, and that our attorneys failed to appreciate the full scope of the invention and that the original claims would possibly preclude coverage of embodiments of the invention that are disclosed and supported by the patent specification, which embodiments are within a scope of coverage to which we are rightfully entitled.

18. Original claim 8 included recitation of “retroinfusing said agent into a vein of said host under conditions sufficient to produce a disruption in said vessel,” whereas the term “vessel” should have been “vein” in order to properly reflect its antecedent.

19. Original claim 11 included recitation of a method that produces “inflammation” [sic] in said “vascular vessel,” whereas it should have recited “inflammation in said vein”.

20. Original claim 15 included recitation of pressure sufficient to produce a disruption “on” said vein, whereas it should have recited pressure sufficient to produce a disruption “in” said vein.

21. Original claim 19 included recitation of a method that produces “inflammation” [sic] in said “vascular vessel,” whereas it should have recited “inflammation in said vein”.

22. Each of claims 8, 11, 15, and 19 are amended in the Preliminary Amendment to correct the formal errors set forth in the preceding four paragraphs.

23. All of the aforementioned errors in the original patent that are being corrected in the reissue application up to the time of filing of this declaration arose without any deceptive intention on the part of any of us.

24. Each of us has reviewed and understands the contents of the above-identified application for Patent Reissue and the Preliminary Amendment filed herewith.

25. Each of us acknowledges the duty to disclose information which is material to the examination of this Application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

26. All statements made herein of our own knowledge are true and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements and the like may jeopardize the validity of this application for reissue or any patent issuing thereon.

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